UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/979,546	11/20/2001	Yasuaki Itoh	46342/56686	6949

21874 7590 07/08/2004

EDWARDS & ANGELL, LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/979,546	ITOH ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Search* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *May4, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *2-4,6 and 7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,5 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/20/01, 11/19/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Election filed May 4, 2004 in response to the Office Action of March 3, 2004 is acknowledged and has been entered. Claims 1-8 are pending in the application. Claim 1 has been amended. Claims 1, 5 and 8 drawn to all limitations other than SEQ ID NO:3 as well as claims 2-4, 6-7 have been withdrawn from further consideration by the Examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 1, 5 and 8 drawn to SEQ ID NO:3, or substantially the same amino acid sequence as SEQ ID NO:3 are currently under prosecution.

2. Applicant's election with traverse of Group 1, claims 1-2, 4-5 and 8 drawn to SEQ ID NO:1, a method of using and a method of making SEQ ID NO:1 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a).

3. Upon review and reconsideration, and in view of the newly amended claim 1, this application contains the following additional inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13:

Groups 13-25, claims 1, 5 and 8 drawn to one of SEQ ID NOs:2-14 or a sequence substantially the same as said one sequence or a salt thereof. It is noted for Applicant's information that this is NOT a species election requirement, but rather a requirement for the election of a distinct Group consisting of a single sequence. Applicant is required to elect a single Group for examination.

Groups 26-38, claim 2, drawn to a method of manufacturing of one of SEQ ID Nos:2-14 or a sequence substantially the same as said one sequence.

It is noted for Applicant's information that this is NOT a species election requirement, but rather a requirement for the election of a distinct Group consisting of a single method of manufacture. Applicant is required to elect a single Group for examination.

Groups 39-51, claim 3, drawn to an antibody against one of SEQ ID Nos:2-14 or a sequence substantially the same as said one sequence. It is noted for Applicant's information that this is NOT a species election requirement, but rather a requirement for the election of a distinct Group consisting of a single antibody. Applicant is required to elect a single Group for examination.

Groups 52-64, claim 4, drawn to a method of screening a compound that promotes the activities of one of SEQ ID Nos:2-14 or a sequence substantially the same as said one sequence. It is noted for Applicant's information that this is NOT a species election requirement, but rather a requirement for the election of a distinct Group consisting of a single method of screening. Applicant is required to elect a single Group for examination.

Groups 65-77, claim 4, drawn to a method of screening a compound that inhibits the activities of one of SEQ ID Nos:2-14 or a sequence substantially the same as said one sequence. It is noted for Applicant's information that this is NOT a species election requirement, but rather a requirement for the election of a distinct Group consisting of a single method of screening. Applicant is required to elect a single Group for examination.

Groups 78-90, claims 6-7, drawn to a compound that promotes the activities of one of SEQ ID Nos:2-14 or a sequence substantially the same as said one sequence. It is noted for Applicant's information that this is NOT a species election requirement, but rather a requirement for the election of a distinct Group consisting of a single compound. Applicant is required to elect a single Group for examination.

Group 91-103, claims 6-7, drawn to a compound that inhibits the activities of one of SEQ ID Nos:2-14 or a sequence substantially the same as said one sequence. It is noted for Applicant's information that this is NOT a species election requirement, but rather a requirement for the election of a distinct Group consisting of a single compound. Applicant is required to elect a single Group for examination.

4. The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus

or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (d), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

As previously set forth, Group 1, claims 1, 2, 5 and 8 drawn to SEQ ID NO:1 and a method of manufacturing SEQ ID NO:1 and a method of using SEQ ID NO:1 is a single general inventive entity.

Groups 13-103 are drawn to additional products and additional methods which are not so linked to Group 1 as to form a single general inventive entity.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

In view of the above, Group 1 is considered the main invention. After that, all other products and methods have been broken out as separate groups (see 37 CAR 1.475(d).).

5. Applicant's amendment of claim 1 to include SEQ ID Nos 2-14 as discussed in the Telephone Interview of April 30, 2004 is noted. Applicant understands that upon amendment of claim 1, a new restriction requirement will be issued wherein each SEQ ID NO: is treated as a separate group. In anticipation of the new restriction requirement, Applicant has stated that should a new restriction requirement be issued, Applicant would elect the group containing SEQ ID NO:3 without traverse.

Therefore, in the interests of compact prosecution, examination of Group 14, SEQ ID NO:3, a kit comprising SEQ ID NO:3 and a pharmaceutical composition comprising SEQ ID NO:3 will herewith commence. Applicant is advised that the response to this requirement to be complete must include confirmation of election of Group 14, even though the requirement be traversed.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1, 5 and 8 are rejected under 35 USC 101 because the claimed invention is not supported by either a specific asserted utility or a substantial utility.

The claims are drawn to SEQ ID NO:3, or substantially the same amino acid sequence as SEQ ID NO:3, a kit comprising SEQ ID NO:3, a pharmaceutical composition comprising SEQ ID NO:3.

The specification teaches that the present inventors have selected cDNAs encoding novel secretory polypeptides rom a large scale cDNA base sequence database (p.2, lines 27-29). The polypeptides of the present invention comprise a signal peptide permitting extracellular secretion of said polypeptide efficiently (p. 5, lines 8-10). The specification further teaches that due to possessing the signal peptide, the polypeptides of the present invention can be secreted efficiently from

cells and then exert important physiological activities as the humoral factor in signal transduction and self-defense (p. 23, lines 21-23). The disclosed utilities for SEQ ID NO:3 include its use as a tissue marker, its use as the marker for detecting differentiation of tissues, conditions or diseases, and metastasis of cancer, as well as its use for fractionation of the corresponding receptor, ligand and the binding protein. The polypeptide can be used to investigate biological activity in the form of a panel for high throughput drug screening as well as chromosome mapping for the study of genetic diseases (para bridging pages 23-24). The polypeptide can also be used as a prophylactic or therapeutic agent for various diseases including cancer, immunological diseases, respiratory tract diseases, digestive tract diseases, cardiovascular diseases, infections, nervous system diseases and psychological diseases (p. 24, lines 5-17). The claimed polypeptide is useful for producing antibodies (p. lines 20-30).

However, neither the specification nor any art of record teaches what SEQ ID NO:3 is, what it does do, do not teach a relationship to any specific diseases or establish any involvement in the etiology of any specific diseases. The asserted utilities for SEQ ID NO:3, such as production of antibodies apply to many unrelated polypeptide structure sequences. Further, although it does not appear that the specification asserts that the secretory property of the claimed SEQ ID NO:3 is a patentable utility, in the interests of compact prosecution, it will be assumed that the secretory property of the claimed SEQ ID NO:3 is inferred as a patentable utility. However, this is not a specific utility because it is well known in the art that the secretory property applies to many unrelated polypeptide structure

sequences. Therefore these two asserted utilities are not considered specific utilities, i.e. they are not specific to SEQ ID NO:3. Additional disclosed utilities for SEQ ID NO:3 include its use as a tissue marker, its use as a marker for detecting differentiation of tissues, conditions, diseases, metastasis of cancer, as well as its use for fractionation of the corresponding receptor, ligand, and its binding protein. However neither the specification nor any art of record teaches which tissue it is a marker for, which specific conditions, diseases, cancer it could be used to detect, or identifies its receptor, ligand, or binding protein. Given the above, it is clear that the invention does not have substantial utility because additional work must be done in order to determine which tissue it is a marker for, which conditions, diseases, cancer it could be used to detect and to identify its receptor, ligand, and binding protein. Further, in the absence of information drawn to specific diseases or conditions, additional work must be done in order to determine the meaning of any effects of any agent upon the activity of the polypeptide found during drug screening or chromosome mapping done, using this polypeptide as a target. In particular, as drawn to a polypeptide which has substantially the same amino acid sequence as SEQ ID NO:3, it is noted that, although not drawn specifically to SEQ ID NO:3, the specification teaches that a polypeptide which has substantially the same amino acid sequence as one of the amino acid sequences in the specification includes an amino acid sequence having not less than about 50% homology, 60% homology, 70% homology 80% homology 90% homology 95% homology compared with that of said amino acid sequence (see page 5, lines 10-15). Given that the claimed SEQ ID NO:3 has neither a specific nor substantial utility it is clear

that a polypeptide which has an amino acid sequence having 50% homology, 60% homology, 70% homology 80% homology 90% homology 95% homology compared with that of SEQ ID NO:3 also does not have either a specific or a substantial utility. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed SEQ ID NO:3. Because the claimed invention is not supported by a specific asserted utility, a substantial utility for the reasons set forth, credibility of any utility cannot be assessed.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

9. Claims 1, 5 and 8 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by a specific utility, a substantial utility for the reasons set forth in the rejection under 35 USC 101 above, one skilled in the art clearly would not know how to use the claimed invention.

10. Claims 1, 5, 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to SEQ ID NO:3 and a polypeptide comprising substantially the same amino acid sequence as SEQ ID NO:3. The specification teaches that SEQ ID NO:3 is encoded by an EST supplied by SmithKline Beecham LTD (see pages 58-59, Examples 1 and 3) and teaches, as set forth above, various uses for the claimed polypeptides.

One cannot extrapolate the teachings of the specification to the enablement of the claims because absent evidence to the contrary, the EST encoding SEQ ID NO:3 is deemed to be an incomplete cDNA. Because the encoding cDNA is not full-length, a sequence prepared from undefined parts of a cDNA clone will not comprise the entire coding region of any particular gene, nor is it clear the partial sequence is even in frame to encode a polypeptide that is expressed *in vivo* or whether a polypeptide fragment encoded by said EST exhibits any activity, even if expressed *in vivo*. The specification provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the claimed putative, apparently fragmentary polypeptide is in fact expressed *in vivo*. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

11. In the event that Applicants might be able to overcome the 35 USC 101 and 112, first paragraph rejections above, claims 1, 5, 8 would still be rejected because the specification, while enabling for a polypeptide comprising SEQ ID NO:3 or a salt thereof does not reasonably provide enablement for a polypeptide comprising substantially the same amino acid sequence of SEQ ID NO:3. The specification does not enable any person

skilled in the art to which it pertains or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1, 5 and 8 are drawn to a polypeptide comprising substantially the same amino acid sequence as SEQ ID NO:3. This includes a whole universe of polypeptides attached to SEQ ID NO:3. As set forth above, the specification teaches that a polypeptide comprising substantially the same amino acid sequence is one with at least 50% homology to SEQ ID NO:3. The claimed polypeptides clearly include polypeptides with deletions, truncations and substitutions of amino acids in SEQ ID NO:3.

One cannot extrapolate the teaching of the specification to the scope of the claims because even if one were to know the function of SEQ ID NO:3, one would not know how to use the claimed variant of SEQ ID NO:3 because protein chemistry is known to be one of the most unpredictable areas of biotechnology. For example, Bowie et al (Science, 1990, 257:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out the instructions of the genome and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (col 1, p. 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are

critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (col 2, p. 1306). The sensitivity of proteins to alterations of even a single amino acid in a sequence are exemplified by Burgess et al (J of Cell Bio. 111:2129-2138, 1990) who teach that replacement of a single lysine reside at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein and by Lazar et al (Molecular and Cellular Biology, 1988, 8:1247-1252) who teach that in transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein. Clearly, with up to 50% dissimilarity, to SEQ ID NO:3, the function of the claimed variants could not be predicted, even if the function of SEQ ID NO:3 were known. Given the above, one of skill in he art would be forced into undue experimentation to practice the claimed invention.

12. In the event that Applicants might be able to overcome the 35 USC 101 and 112, first paragraph rejections above, claim 8 would still be rejected under 35 USC 112, first paragraph because the specification, while enabling for a polypeptide comprising SEQ ID NO:3 or a polypeptide having substantially the same amino acid sequence as SEQ ID NO:3 or a salt thereof does not reasonably provide enablement for a pharmaceutical composition comprising SEQ ID NO:3 or a polypeptide comprising

substantially the same amino acid sequence of SEQ ID NO:3. The specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The specification teaches as set forth above, that is that the polypeptides of the invention are useful for prophylactic and therapeutic applications in a laundry list of diseases and conditions.

One cannot extrapolate the teaching of the specification to the scope of the claims because inherent to a pharmaceutical compositions is an *in vivo* use thereof in the management of disease. However, the instant specification provides no information as to which diseases might be amenable to treatment with the claimed polypeptides. The specification does not provide guidance by way of general methods or working examples which teach the feasibility of *in vivo* treatment or prophylaxis using for the claimed polypeptides. Because *in vivo* administration of a pharmaceutical composition may involve different routes, dosages, schedules, etc., and also exposes the composition to complex environments including blood cells and proteins, and also diverse organs such as the liver, lungs, kidney, and spleen, the fate and activity of the claimed polypeptides is unpredictable regarding its ability to effectively treat or prevent any disease, even if the disease to be treated were to be known. Given the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

13. Claims 1, 5, 8 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NO:3 and therefore the written description is not commensurate in scope with the claims drawn polypeptides having substantially the same amino acid sequences of SEQ ID NO:3. It is noted that the specification appears to define "substantially the same" as a homology of at least 50%.

The specification discloses a putative polypeptide, SEQ ID NO:3. However, the claims are drawn to a whole universe of polypeptides that are attached to SEQ ID NO:3. The instant disclosure of a single species of polypeptide does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including polypeptides with substitutions insertions and deletions of the amino acid sequence of SEQ ID NO:3. Although drawn to the DNA arts, the findings in *Regents of the University of California v. Eli Lilly & Co* are pertinent to the instant rejection. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus

of polypeptides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. Further, there is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of a single specific polypeptide sequence is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed and that the claimed subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraph of 35 U.S.C. 102 that forms the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

15. Claims 1, 8 are rejected under 35 USC 102(e) as being anticipated by US Patent No. 5,962,319.

The claims are drawn to a polypeptide comprising substantially the same amino acid sequence as SEQ ID NO:3, a pharmaceutical composition comprising said compound.

It is noted that the preamble recitation of claim 8, a pharmaceutical composition, is viewed as an intended use of the claimed polypeptide and therefore carries no patentable weight. The claims read on the product claimed, *per se*, that is a polypeptide comprising substantially the same amino acid sequence as SEQ ID NO:3.

US Patent No. 5,962,319 specifically teaches a polypeptide comprising SEQ ID NO:6 which has 98.2% identity to 97.9% of SEQ ID NO:3 of the instant invention (see claim 1 and sequence database search us-09-979-546a-3.rai, result 1, attached hereto).

Claim Rejections - 35 USC § 103

16. The following is a quotation of the appropriate paragraph of 35 U.S.C. 103 that forms the basis for the rejections under this section made in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claim 5 is rejected under 35 USC 103 as being unpatentable over US Patent No. 5,962,319.

The claim is drawn to a kit comprising a polypeptide comprising substantially the same amino acid sequence as SEQ ID NO:3 for screening for a compound or salt that either inhibits or promotes the activities of SEQ ID NO:3.

It is noted that the preamble recitation of claim 5, a kit for screening for a compound or salt that either inhibits or promotes the activities of SEQ ID NO:3, is viewed as an intended use of the claimed kit and therefore carries no patentable weight. The claim reads on the product claimed, *per se*, that is a polypeptide comprising substantially the same amino acid sequence as SEQ ID NO:3.

US Patent No. 5,962,319 teaches as set forth above and further teaches that SEQ ID NO:6 is a human-Th-1 protein (see claim 1) and that

human-Th-1 protein is useful for specifying or correcting the polarization of the Th1/Th2 subsets of helper T cells (see abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a kit ,useful to characterize and to analyze the activity of the human-Th-1 protein of US Patent No. 5,962,319, comprising SEQ ID NO:6 because the patent specifically teaches that the protein is useful for specifying or correcting the polarization of the Th1/Th2 subsets of helper T cells. One of ordinary skill in the art at the time the invention was made would have been motivated to make a kit useful to characterize and for the analysis of the activity of the human-Th-1 protein of US Patent No. 5,962,319 comprising SEQ ID NO:6 because standard kits enhance the probability of the reproducibility and efficiency of the analysis process.

18. No claims allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the in examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 872-9306.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
June 30, 2004